

WHAT IS CLAIMED IS:

- 1 1. An expression vector, said vector comprising an expression cassette
2 comprising two components:
 - 3 (a) a eukaryotic promoter and a first RNA polymerase promoter operably
4 linked to a nucleic acid encoding a secretable RNA polymerase having a secretion domain,
5 and a first internal ribosome entry site (IRES); and
6 (b) a second RNA polymerase promoter operably linked to a nucleic acid
7 encoding a product of interest and a second internal ribosome entry site.
- 1 2. The expression vector of claim 1, wherein said eukaryotic promoter is
2 a cytomegalovirus promoter.
- 1 3. The expression vector of claim 1, wherein said RNA polymerase is a
2 non-host RNA polymerase.
- 1 4. The expression vector of claim 1, wherein said RNA polymerase is a
2 T7 RNA polymerase.
- 1 5. The expression vector of claim 1, wherein said first IRES and said
2 second IRES are the same.
- 1 6. The expression vector of claim 1, wherein said first IRES and said
2 second IRES are different.
- 1 7. The expression vector of claim 1, wherein said first IRES and said
2 second IRES are from encephalomyocarditisvirus.
- 1 8. The expression vector of claim 1, wherein said secretion domain is a
2 member selected from the group consisting of: SEQ ID NOS: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11,
3 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40,
4 41, 42, 43, 44, and 45.
- 1 9. The expression vector of claim 1, wherein said product of interest is a
2 therapeutic product.

1 10. The expression vector of claim 9, wherein said therapeutic product is a
2 member selected from the group consisting of: a protein, a nucleic acid, an antisense nucleic
3 acid, ribozymes, tRNA, siRNA, and an antigen.

1 11. A host cell comprising the expression vector of claim 1.

1 12. A lipid-nucleic acid composition comprising:
2 a nucleic acid-lipid particle comprising a lipid portion and a nucleic acid
3 portion,
4 wherein said nucleic acid portion comprises an expression cassette comprising
5 two components:

6 (a) a eukaryotic promoter and a first RNA polymerase promoter operably
7 linked to a nucleic acid encoding a secretable RNA polymerase having a secretion domain,
8 and a first internal ribosome entry site; and

9 (b) a second RNA polymerase promoter operably linked to a nucleic acid
10 encoding a product of interest and a second internal ribosome entry site.

1 13. The lipid-nucleic acid composition of claim 12, wherein said nucleic
2 acid-lipid particle is a serum-stable nucleic acid-lipid particle comprising a nucleic acid fully
3 encapsulated within said lipid portion.

1 14. The lipid-nucleic acid composition of claim 12, wherein said lipid
2 portion comprises a cationic lipid, a non-cationic lipid; and a polyethyleneglycol-lipid
3 conjugate.

1 15. The lipid-nucleic acid composition of claim 14, wherein said cationic
2 lipid is a member selected from the group consisting of: N,N-dioleoyl-N,N-
3 dimethylammonium chloride (DODAC), N,N-distearyl-N,N-dimethylammonium bromide
4 (DDAB), N-(1-(2,3-dioleoyloxy)propyl)-N,N,N-trimethylammonium chloride (DOTAP), N-
5 (1-(2,3-dioleoyloxy)propyl)-N,N,N-trimethylammonium chloride (DOTMA), and N,N-
6 dimethyl-2,3-dioleoyloxy)propylamine (DODMA), and a mixture thereof.

1 16. The lipid-nucleic acid composition of claim 14, wherein said non-
2 cationic lipid is a member selected from the group consisting of
3 dioleoylphosphatidylethanolamine (DOPE), palmitoylloleoylphosphatidylcholine (POPC),

4 egg phosphatidylcholine (EPC), distearoylphosphatidylcholine (DSPC), cholesterol, and a
5 mixture thereof.

1 17. The lipid-nucleic acid composition of claim 14, wherein said cationic
2 lipid comprises from about 2% to about 60% of the total lipid present in said particle.

1 18. The lipid-nucleic acid composition of claim 14, wherein said non-
2 cationic lipid comprises from about 5% to about 90% of the total lipid present in said particle.

1 19. The lipid-nucleic acid composition of claim 14, wherein said PEG-
2 lipid conjugate comprises from 1% to about 20% of the total lipid present in said particle.

1 20. The lipid-nucleic acid composition of claim 14, wherein said non-
2 cationic lipid is DSPC.

1 21. The lipid-nucleic acid composition of claim 14, further comprising
2 cholesterol.

1 22. The lipid-nucleic acid composition of claim 21, wherein the cholesterol
2 comprises from about 10% to about 60% of the total lipid present in said particle.

1 23. The lipid-nucleic acid composition of claim 14, wherein
2 the cationic lipid comprises 7.5% of the total lipid present in said particle;
3 the non-cationic lipid comprises 82.5% of the total lipid present in said
4 particle; and
5 the PEG- lipid conjugate comprises 10% of the total lipid present in said
6 particle.

1 24. The lipid-nucleic acid composition of claim 14, wherein the nucleic
2 acid-lipid particle comprises:
3 DODMA;
4 DSPC; and
5 a PEG- lipid conjugate.

1 25. The lipid-nucleic acid composition of claim 24, further comprising
2 cholesterol.

3 26. A method of expressing a nucleic acid encoding a product of interest in
4 a cell, said method comprising:

5 introducing into a cell an expression vector comprising an expression cassette
6 comprising two components:

7 (a) a eukaryotic promoter and a first RNA polymerase promoter operably
8 linked to a nucleic acid encoding a secretable RNA polymerase having a secretion domain,
9 and a first internal ribosome entry site; and

10 (b) a second RNA polymerase promoter operably linked to a nucleic acid
11 encoding a product of interest and a second internal ribosome entry site.

1 27. The method of claim 26, wherein said RNA polymerase is a T7 RNA
2 polymerase.

1 28. The method of claim 26, wherein said secretion domain is a member
2 selected from the group consisting of: SEQ ID NOS: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13,
3 14, 15, 16, 17, 18, 19, 20, 21, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42,
4 43, 44, and 45.

1 29. The method of claim 26, wherein said expression vector is fully
2 encapsulated in a lipid portion of a serum stable nucleic acid-lipid particle.

1 30. The method of claim 26, wherein said product of interest is a
2 therapeutic product.

1 31. The method of claim 26, wherein said therapeutic product is a member
2 selected from the group consisting of: a protein, a nucleic acid, an antisense nucleic acid,
3 ribozymes, tRNA, siRNA, and an antigen.

1 32. A method of delivering a nucleic acid encoding a product of interest to
2 a cell, said method comprising:

3 introducing into the cell an expression vector comprising an expression
4 cassette comprising two components:

5 (a) a eukaryotic promoter and a first RNA polymerase promoter operably
6 linked to a nucleic acid encoding a secretable RNA polymerase having a secretion domain,
7 and a first internal ribosome entry site; and

8 (b) a second RNA polymerase promoter operably linked to a nucleic acid
9 encoding a product of interest and a second internal ribosome entry site.

1 33. The method of claim 32, wherein said cell is in a mammal.

1 34. The method of claim 33, wherein said mammal is a human.

1 35. A method of treating a disease in a subject, comprising:
2 administering a therapeutically effective amount of an expression cassette
3 comprising two components:

4 (a) a eukaryotic promoter and a first RNA polymerase promoter operably
5 linked to a nucleic acid encoding a secretable RNA polymerase having a secretion domain,
6 and a first internal ribosome entry site; and

7 (b) a second RNA polymerase promoter operably linked to a nucleic acid
8 encoding a therapeutic product and a second internal ribosome entry site.

1 36. The method of claim 35, wherein said subject is a mammal.

1 37. The method of claim 36, wherein said mammal is a human.

1 38. The method of claim 35, wherein said expression vector is fully
2 encapsulated in a lipid portion of a serum stable nucleic acid-lipid particle.

1 39. The method of claim 35, wherein said disease is a member selected
2 from the group consisting of: a cancer, an autoimmune disease, a cardiovascular disease, a
3 viral disease, a bacterial disease, and an inflammatory disease.

1 40. An isolated purified nucleic acid comprising the sequence set forth in
2 SEQ ID NO: 46, 50, or 51.